

NOV - 9 2000

510(k) Summary  
100S/100LC/485 Anser  
Pie Medical

## 510(k) Summary

The following safety and effectiveness summary has been prepared pursuant to requirement for 510(k) summaries specified in 21CFR§807.92(a).

### 807.92(a)(1)

#### Submitter Information

Colleen Hittle, Official Correspondent  
8000 Castleway Drive  
Indianapolis, IN 46250  
Phone: (317) 849-1916  
Facsimile: (317) 5779070

Contact Person: Colleen Hittle

Date: July 21, 2000

### 807.92(a)(2)

Trade Name: 100S/100LC/485 Anser Ultrasound Imaging Systems  
Common Name: Ultrasound Imaging System  
Classification Name(s): Ultrasonic pulsed doppler imaging system 892.1550  
Ultrasonic pulsed echo imaging system 892.1560  
Classification Number: 90IYO

### 807.92(a)(3)

#### Predicate Device(s)

Pie Medical	480	K911584
	250	K915647

Additional Substantial Equivalence Information is provided in the following substantial Equivalence Comparison Table.

510(k) Summary  
100S/100LC/485 Anser  
Pie Medical

807.92(a)(5)

### **Device Description**

### **Intended Use(s)**

Pie Medical's 100S/100LC/485 Anser ultrasound systems used are to perform general diagnostic ultrasound studies.

510(k) Summary  
100S/100LC/485 Anser  
Pie Medical

Comparison Chart for Substantial Equivalence

	Pie MERA Endorectal Probe (K911043)	PiE 400/450 (Predicate to 1150, cleared via K874192)	PiE 1150 (Predicate to 250, cleared via K900469)	PiE 250 (Predicate to 240, cleared via K915647)	PiE 100S To be cleared with this submission	PiE 100LC To be cleared with this submission	PiE 480 (Predicate to 485 Anser, cleared via 510(k) 911584)	PiE 485 Anser To be cleared with this submission
Technology	Annular	Linear	Linear Curved Mechanical Annular	Annular Curved Linear	Annular	Linear Curved	Linear	Curved/Linear
Modes	B, B+M, M	B, B+M, M	B, B+M, M	B, B+M, M	B, B+M, M	B, B+M, M	B, B+B, B+M, M	B, B+B, B+M, M
Frequencies	5.0 – 7.5 MHz	3.5 – 7.5 MHz	3.5 – 7.5 MHz	3.5-7.5 MHz	3.5-7.5 MHz	3.5-8MHz	3.5 – 7.5 MHz	3.5 – 8 MHz
Applications	Urological Transrectal	Abdominal Fetal Pediatric Small Organs Intraoperative Neonatal Cephalic	Abdominal Fetal Pediatric Small Organs Intraoperative	Abdominal Small Organ Intraoperative Pediatric Peripheral Vascular Fetal	Abdominal Transvaginal Cardiac Fetal Small Organs Transrectal Pediatric Peripheral Vascular Intraoperative Musculoskeletal	Abdominal Transvaginal Fetal Pediatric Small Organs Transrectal Intraoperative Peripheral Vascular Cardiac Musculoskeletal	Abdominal Small Organ Pediatric Fetal	Abdominal Small Organ Transvaginal Transrectal Intraoperative Neonatal Cephalic Pediatric Peripheral Vascular Fetal Musculoskeletal



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV - 9 2000

Pie Medical  
c/o Colleen Hittle  
Official Correspondent  
The Anson Group  
800 Castleway Drive  
Indianapolis, IN 46250

Re: K002357  
100S,100LC, and 485 Anser Ultrasound Imaging Systems  
Regulatory Class: II  
21CFR892.1560/Procode: 90 IYO  
21CFR892.1570/Procode: 90 ITX  
Dated: October 30, 2000  
Received: October 31, 2000

Dear Ms. Hittle:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the ultrasound systems listed below, as described in your premarket notification:

Transducer Model Numbers for the 100S Ultrasound Imaging System

402144  
402154  
402155  
402156

Transducer Model Numbers for the 100LC Ultrasound Imaging System

401612  
401664  
401665  
401667  
401669  
401671  
401788  
410054

Transducer Model Numbers for the 485 Anser Ultrasound Imaging System

401612  
401664  
401665  
401667  
401669  
401788  
410054

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

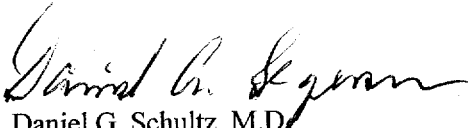
This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Page -3- Ms. Hittle

If you have any questions regarding the content of this letter, please contact Paul M. Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,

*for* 

Daniel G. Schultz, M.D.  
Captain, USPHS  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure(s)

# 100S System

## Appendix F

### Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E						E	
Abdominal		E	E						E	
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)		E	E						E	
Neonatal Cephalic		N	N						N	
Adult Cephalic										
Cardiac		N	N						N	
Transesophageal										
Transrectal		E	E						E	
Transvaginal		E	E						E	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast); Applicable Combined Modes: B+B; B+M

Prescription Use  
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K002357

## Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E						E	
Abdominal		E	E						E	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N						N	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

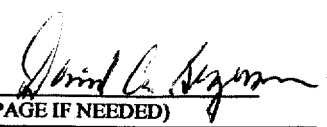
N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Applicable Combined Modes: B+B; B+M

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K002357



## Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E						E	
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		E	E						E	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranoesophageal										
Transrectal										
Transvaginal		E	E						E	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast); Applicable Combined Modes: B+B; B+M

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K002357

## Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

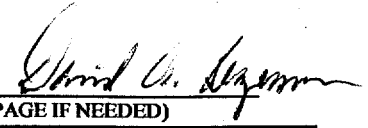
Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E						E	
Abdominal		E	E						E	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)		E	E						E	
Neonatal Cephalic		N	N						N	
Adult Cephalic										
Cardiac										
Traneseophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast); Applicable Combined Modes: B+B; B+M

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  
(Per 21 CFR 801.109)
  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT  
 and Radiological Devices

510(k) Number K002357

## Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		E	E						E	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranosophageal										
Transrectal		E	E						E	
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast); Applicable Combined Modes: B+B; B+M

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  
(Per 21 CFR 801.109)

David A. Szymanski

(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K002357

# 100LC System

Appendix F

## Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E						E	
Abdominal		E	E						E	
Intraoperative Abdominal		N	N						N	
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)		E	E						E	
Neonatal Cephalic		N	N						N	
Adult Cephalic										
Cardiac		N	N						N	
Transesophageal										
Transrectal		E	E						E	
Transvaginal		E	E						E	
Transurethral										
Intravascular										
Peripheral Vascular		E	E						E	
Laparoscopic										
Musculo-skeletal Conventional		N	N						N	
Musculo-skeletal Superficial		N	N						N	
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast)

Applicable combined modes: B+B; B+M

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*David A. Szymanski*

(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K0D2357

Prescription Use ✓  
(Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

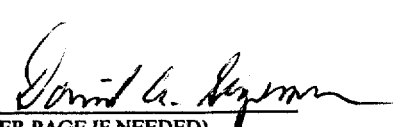
Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E						E	
Abdominal		E	E						E	
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N						N	
Traneseophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined modes = B+B; B+M

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)
  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices
510(k) Number K002357

## Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E						E	
Abdominal		E	E						E	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										


N= new indication; P= previously cleared by FDA; E= added under Appendix E

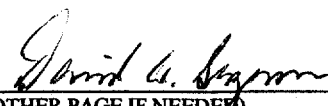
Additional Comments:

Applicable combined modes: B+B; B+M

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K002357

## Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E						E	
Abdominal		E	E						E	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N						N	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

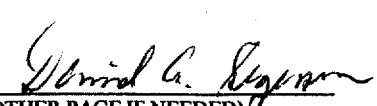
N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Applicable combined modes: B+B; B+M

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ONE)

Prescription Use ✓  
(Per 21 CFR 801.109)
  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices
510(k) Number K002357

## Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		E	E						E	
Intraoperative Abdominal		N	N						N	
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)		E	E						E	
Neonatal Cephalic		N	N						N	
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		E	E						E	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast)

Applicable combined modes: B+B; B+M

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  
(Per 21 CFR 801.109)

*David C. Korman*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices

510(k) Number K002357



## Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N						N	
Abdominal		E	E						E	
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Applicable combined modes: B+B; B+M

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K002357Prescription Use  
(Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E						E	
Abdominal										
Intraoperative Abdominal		N	N						N	
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)		E	E						E	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		E	E						E	
Laparoscopic										
Musculo-skeletal Conventional		N	N						N	
Musculo-skeletal Superficial		N	N						N	
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

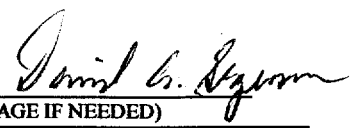
Additional Comments: Small Organs (specifically, thyroid, testicles, and breast)

Applicable combined modes: B+B; B+M

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

 Prescription Use ✓  
 (Per 21 CFR 801.109)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K002357

## Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		N	N						N	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N	N						N	
Transvaginal		E	E						E	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast)

Applicable combined modes: B+B; B+M

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K002357Prescription Use  
(Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		E	E						E	
Intraoperative Abdominal		N	N						N	
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)		E	E						E	
Neonatal Cephalic		E	E						E	
Adult Cephalic										
Cardiac										
Traneseophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N						N	
Laparoscopic										
Musculo-skeletal Conventional		N	N						N	
Musculo-skeletal Superficial		N	N						N	
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast)

Applicable combined modes: B+B; B+M

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

✓  
**Prescription Use**  
 (Per 21 CFR 801.109)

*David A. Sygm*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K002357

# 485 Anser System

Appendix F

## Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E						E	
Abdominal		E	E						E	
Intraoperative Abdominal		E	E						E	
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)		E	E						E	
Neonatal Cephalic		E	E						E	
Adult Cephalic										
Cardiac		N	N						N	
Transesophageal										
Transrectal		E	E						E	
Transvaginal		E	E						E	
Transurethral										
Intravascular										
Peripheral Vascular		E	E						E	
Laparoscopic										
Musculo-skeletal Conventional		N	N						N	
Musculo-skeletal Superficial		N	N						N	
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast)

Applicable combined modes: B+B; B+M

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

*David L. Nelson*  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K002357

## Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E						E	
Abdominal		E	E						E	
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N						N	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined modes = B+B; B+M

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

 Prescription Use ✓  
 (Per 21 CFR 801.109)

*David A. Berger*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K002357

## Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E						E	
Abdominal		E	E						E	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Applicable combined modes: B+B; B+M

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

 Prescription Use ✓  
 (Per 21 CFR 801.109)

 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices
510(k) Number R002357

## Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E						E	
Abdominal		E	E						E	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N						N	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Applicable combined modes: B+B; B+M

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

 Prescription Use ✓  
 (Per 21 CFR 801.109)

 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K002357



## Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		E	E						E	
Intraoperative Abdominal		E	E						E	
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)		E	E						E	
Neonatal Cephalic		E	E						E	
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		E	E						E	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast)

Applicable combined modes: B+B; B+M

Prescription Use                       
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number

K002357

## Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		E	E						E	
Abdominal		E	E						E	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Applicable combined modes: B+B; B+M

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K002357Prescription Use ✓  
(Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		E	E						E	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		E	E						E	
Transvaginal		E	E						E	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast)

Applicable combined modes: B+B; B+M

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*David A. Segerson*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices

510(k) Number 1002357

Prescription Use ✓  
 (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		E	E						E	
Intraoperative Abdominal		E	E						E	
Intraoperative Neurological										
Pediatric		E	E						E	
Small Organ (specify)		E	E						E	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Traneseophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		E	E						E	
Laparoscopic										
Musculo-skeletal Conventional		N	N						N	
Musculo-skeletal Superficial		N	N						N	
Other										

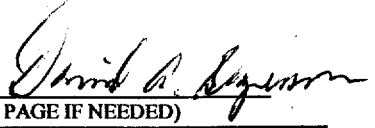
N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast)

Applicable combined modes: B+B; B+M

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  
(Per 21 CFR 801.109)
  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices
510(k) Number 4002357